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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,914	07/16/2003	Christoph Benning	MSU-07769	8436

7590 05/19/2006

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EXAMINER

BAGGOT, BRENDAN O

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,914

Applicant(s)

BENNING ET AL.

Examiner

Brendan O. Baggot

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-12,15-24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1,11 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction / Election

1. The Office acknowledges the receipt of Applicant's restriction election, filed March 3, 2006. Applicant elects Group I, claims 1, 2, 5-12, 15-24, 26-29, drawn to SEQ ID NO: 44 encoding SEQ ID NO: 45 with traverse.

Applicant traverses the restriction between SEQ ID NO:44 and SEQ ID NO:49, stating primarily that 1) no undue search burden presented; 2) both sequences are in the same enzyme class and are both nucleic acids; 3) USPTO Director allows for examination of ten sequences; and 4) these two sequences are in a proper Markush grouping as they are closely related and few and number.

Applicant's traversals have been carefully considered but are deemed unpersuasive for the following reasons. SEQ ID NO:44 has 2727 bases and was isolated from *Chlamydomonas reinhardtii* while SEQ ID NO:49 has 1947 bases and was isolated from *Neurospora crassa*. Examination of both sequences would require separate database searches for each of the sequences and therefore would create undue burden on the Office. Furthermore, a sequence search of SEQ ID NO:44 shows that it has a 3.7% sequence identity to SEQ ID NO:49. Thus, these sequences are not "closely related" as asserted by Applicant. While the Office may have had the discretion to examine up to ten independent sequences in the past, Office resources can no longer support such searches. Additionally, with regard to Applicant's traversal (2) above, it does not appear that Applicant is relying on these sequences being in the same enzyme class and nucleic acids for patentability, as one Bta1 enzyme sequence does not render obvious

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another Bta1 enzyme sequence and one nucleic acid sequence does not render obvious another nucleic acid sequence. Claims 1-30 are pending. Claims 3, 4, 13, 14, 25, and 30 are nonelected. Claims 1, 2, 5-12, 15-24, 26-29 drawn to SEQ ID NO: 44 encoding SEQ ID NO:45, are examined in the instant application. Non-elected subject matter should be removed from the examined claims. This restriction is made FINAL.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed 4/21/06, is attached to the instant Office Action.

Drawings

3. The drawings are acceptable for examination.

Claim Objections

4. Claims 6 and 16 are objected for the following reasons: Claims 6 and 16 are duplicates. It appears that Applicant intends for Claim 16 to depend from Claim 15 and not claim 5.

Claim 1, 11, 21 contain language drawn to non-elected sequences. Non-elected subject matter, e.g., "selected from the group. . .", should be cancelled from the claims.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. §101

5. 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 2, 12, 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 2, 12, 21, directed to an unpurified RNA transcribed from the DNA of Claim 1, reads on a product of nature. The mature transcribed mRNA from the DNA of claim 1 is present in nature as shown by the presence in nature of the instant protein.

Claim Rejections - 35 U.S.C. §112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 21, 26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

In Claim 21, 26, "DGTS synthetic activity" is unclear. Does the applicant mean DGTS synthesizing activity or a novel DGTS enzyme activity different from the native enzyme activity?

The term "oligonucleotide" is understood by those skilled in the art to be a short nucleotide sequence. Since SEQ ID NO:44 contains 2727 bases, it is unclear what "oligo" is intended to mean.

Clarification and/or correction are required.

Claim Rejections - 35 U.S.C. §112, first paragraph, written description⁹. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 21-24, 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims reciting hybridization conditions or 95% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass Bta1 homologs from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and other Bta1 homologs, absent further guidance. Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention at the time of filing. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices', p. 1099-1111.

It is well established that sequence similarity is not sufficient to determine functionality of a coding sequence. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar function's" (the last sentence of the first paragraph of page 2484). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph).

In addition, Smith et al (Nature Biotechnology 15: 1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (See the second full paragraph of the second column of page 132, for example).

The Federal Circuit has clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus,

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Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described.

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Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See The Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Accordingly, Claims 21-24 and 26-29 are rejected.

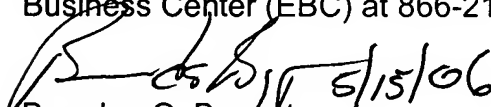
Remarks

11. No claim is allowed. SEQ ID NO: 44 and 45 are deemed free of the prior art.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 5/15/06
Brendan O. Baggot
Patent Examiner
Art Unit 1638

 5/15/06
PHUONG T. BUI
PRIMARY EXAMINER

bob